

be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central record-keeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system downtime, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the ap-

propriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two applications described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use an application that meets the requirements of part 1311 of this chapter.

[75 FR 16308, Mar. 31, 2010]

#### **§ 1306.23 Partial filling of prescriptions.**

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5320, Feb. 13, 1986; 62 FR 13965, Mar. 24, 1997]

#### **§ 1306.24 Labeling of substances and filling of prescriptions.**

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (*i.e.* the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to

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the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV, or V is dispensed at one time;

(2) The controlled substance listed in Schedule III, IV, or V is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV, or V; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(d) All prescriptions for controlled substances listed in Schedules III, IV, and V shall be kept in accordance with § 1304.04(h) of this chapter.

[62 FR 13965, Mar. 24, 1997, as amended at 68 FR 37411, June 24, 2003]

### **§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.**

(a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Transfers are subject to the following requirements:

(1) The transfer must be communicated directly between two licensed pharmacists.

(2) The transferring pharmacist must do the following:

(i) Write the word "VOID" on the face of the invalidated prescription; for

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electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(ii) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(3) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist pursuant to § 1306.21(a), the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to § 1306.05 and include:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescription.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s).

(v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(4) For electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

(i) The date of the original dispensing.

(ii) The number of refills remaining and the date(s) and locations of previous refills.

(iii) The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.